UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address; COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

70 7590 02/26/2008

HOWSON AND HOWSON SUITE 210 501 OFFICE CENTER DRIVE FT WASHINGTON, PA 19034 EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT PAPER NUMBER

1645 DATE MAILED: 02/26/2008

APPEZCATION NO. FELING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFRMATION NO.

09806.370 10903/2001 Randul K. Holmes 33,383-00 8568
TITLE OF INVESTION: MUTANT CHOLERA HOLOTOXIN AS AN ADJUVANT

APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$0	\$0	\$1440	05/27/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

appropriate. All further indicated unless correcte maintenance fee notifical	correspondence includir ed below or directed oth	or transmitting the 1880 ig the Patent, advance of herwise in Block 1, by (a	rders and notification of n i) specifying a new corres	naintenance fees w pondence address;	ill be and/or	mailed to the current r (b) indicating a sepa	correspondence address as arate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
HOWSON AN SUITE 210 501 OFFICE CE	ENTER DRIVE	/2008	I boo	Cert	ificate	of Mailing or Trans	
FT WASHINGT	ON, PA 19034						(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
09/806,370 TITLE OF INVENTION	10/03/2001 : MUTANT CHOLERA	HOLOTOXIN AS AN A	Randall K. Holmes DJUVANT			33,383-00	8568
APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$0	\$0		\$1440	05/27/2008
EXAM	INER	ART UNIT	CLASS-SUBCLASS				
PORTNER, VIRGINIA ALLEN		1645	424-201100				
1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/12) attached. The Address from PTO/SB/12 attached. The Address' indication (or "Fee Address' Indication form PTO/SB/14; Rev 0.3-02 or more execut) attached. Use of a Customer Number is required. AMBIENT ASSIGNEE ANDME AND RESIDENCE DATA TO BE PRINTED ON			(1) the names of up to or agents OR, alternativ (2) the name of a singly registered attorney or a 2 registered patent attor listed, no name will be ITHE PATENT (print or typ	e name of a single firm (having as a member a 2 rered attorney or agent) and the names of up to stered patient attorneys or agents. If no name is 3 no name will be printed.			
(A) NAME OF ASSIG	SNEE	ified below, no assignee sletion of this form is NO categories (will not be pr	(B) RESIDENCE: (CITY	and STATE OR C	OUNT	RY)	ocument has been filed for
4a. The following fee(s) are submitted: Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies			D. Payment of Fee(s): (Plea A check is enclosed. Payment by credit can The Director is hereby overpayment, to Depo	d. Form PTO-2038	is atta	sched.	
	s SMALL ENTITY state	is. See 37 CFR 1.27.	☐ b. Applicant is no long				
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than to Office.	ne applicant; a regis	tered	attorney or agent; or th	ne assignee or other party in
Authorized Signature				Date			
Typed or printed name				Registration N			
This collection of inform an application. Confident submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C tiality is governed by 35 I application form to the ions for reducing this but firginia 22313-1450. DC 13-1450.	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary den, should be sent to the ONOT SEND FEES OR	on is required to obtain or r 1.14. This collection is est depending upon the indiv e Chief Information Office COMPLETED FORMS TO	etain a benefit by the imated to take 12 m idual case. Any co r, U.S. Patent and D THIS ADDRESS	e pub ninute: nment Frader SEN	lic which is to file (and s to complete, including s on the amount of tin nark Office, U.S. Dep D TO: Commissioner	d by the USPTO to process) ag gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450,

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

ss: COMMISSIONER FOR PATENTS P O Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

DATE MAILED: 02/26/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/806,370	10/03/2001	Randall K. Holmes	33,383-00	8568	
270	7590 02/26/2008		EXAMINER		
HOWSON AND HOWSON			PORTNER, VII	RGINIA ALLEN	
SUITE 210			ART UNIT	PAPER NUMBER	
501 OFFICE CEI FT WASHINGTO			1645		

Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)	_
09/806,370	HOLMES ET AL.	
Examiner	Art Unit	٦
GINNY BORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable. PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative

- of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to
- The allowed claim(s) is/are 3-11,14-17,28-37 and 39-44.
- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - b) ☐ Some* c) ☐ None of the: a) \square All
 - 1.

 Certified copies of the priority documents have been received.
 - 2.

 Certified copies of the priority documents have been received in Application No. ____
 - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received:

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date
 - (b) I including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08). Paper No./Mail Date
- 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. X Examiner's Amendment/Comment
- 8. T Examiner's Statement of Reasons for Allowance
- Other substance of the interview.

Application/Control Number: 09/806,370 Page 2

Art Unit: 1645

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or
additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR
 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the
payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with the attorney of record, Mr. Robert Duminiak for Ms. Mary Bak, Registration Number 31,215 on February 14, 2008. Please see Appellant's statement of the substance of the interview attached herewith.

The application has been amended as follows:

Attached please find a copy of claims indicated as containing allowable subject matter amended into independent form, and no longer depending upon a rejected based claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/806,370 Page 3

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/vgp/

Examiner, Art Unit 1645 February 14, 2008

/Shanon A. Foley/

Supervisory Patent Examiner, Art Unit 1645